

20. (Amended) The method of claim 18 wherein the chemotherapeutic agent is [mitoxanthrone] mitoxantrone, prednisone, estramustine, melphalan, vinblastine or a combination thereof.
21. (Amended) The method of claim 19 [12] wherein the chemotherapeutic agent is an anti-androgen.
22. The method of claim 21 wherein the anti-androgen is bicafutamide, nilutamide, flutamide, cycloproterone acetate or a combination thereof.
23. The method of claim 21 wherein the anti-androgen is leuprolide acetate, goserelin acetate or a combination thereof.

REMARKS

Applicant has carefully reviewed and considered the Office Action mailed on May 2, 2002, and the references cited therewith. The amendments to the specification at pages 3-4 and page 8 are to clarify subject matter that applicants regard as their invention. The amendments are to clarify that the second recitation of "R⁸" at page 4, line 2 and page 8, line 18, recites additional Z terms. The specification has been amended to cancel the second recitation of "R⁸" in each instance for clarity.

In addition, the group $\text{OCH}_2\text{CH}_2\text{N}(\text{CH}_3)_3^+$ has been added to the paragraphs at page 4, line 4 and page 8, line 20, respectively, to provide antecedent basis for this group. This group is supported by claim 5, of the original claims. No new subject matter is added.

Claims 1, 10, 20 and 21 are amended, and claims 1-23 are now pending in this application. The amendments to claim 1 reflect the changes that have been made in the above-identified paragraphs from the specification. The terms amino, lower alkylamino, di(lower alkyl)amino, and phenylamino are added to claim 1. These groups are supported by the specification at page 8, lines 17-18. These amendments did not narrow the scope of the claim. Thus, the claim is entitled to a full range of equivalents.

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In addition, the provisos are added to claim 1 to distinguish the claimed compounds from those disclosed in example 169 of document D1, DE 22 35 340 A (U.S. Patent No. 3,843,681) and compounds 3, 4, 9, and 10 disclosed in document D2, Brenna *et al.* (cited in the International Search Report). The Examiner is requested to note that the amendment of claim 1 herein does not surrender any equivalent to which the other substituents may be entitled. Claim 10 is amended to include the compounds of formula (I). Claim 21 is amended to change the dependency. The term melphalan added to claim 20 is supported by the specification at page 15, line 20. No new subject matter is added.

Information Disclosure Statement

Applicant respectfully requests that a copy of the 1449 Form, listing all references that were submitted with the Information Disclosure Statement filed on February 15, 2001, marked as being considered and initialed by the Examiner, be returned with the next official communication. Unfortunately, Applicants did not receive page 4 of the Form 1449 with the Office Action mailed May 2, 2002.

Double Patenting Rejection

Claims 1, 6, 10, 11, 14, and 15 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, 12, and 20 of co-pending U.S. patent application No. 09/360,020; and over claims 1, 3, 4, and 13 of co-pending U.S. patent application No. 09/589,476. This rejection is respectfully traversed.

Applicants note that neither U.S. patent application No. 09/360,020 nor U.S. patent application No. 09/589,476 has been allowed. Upon notification of otherwise allowable subject matter in this application or in either of the co-pending applications, Applicants will file a terminal disclaimer or take other appropriate action in this or the other application(s).

Accordingly, reconsideration and withdrawal of the provisional rejection of claims 1, 6, 10, 11, 14, and 15 under the judicially created doctrine of obviousness-type double patenting is proper and is requested.

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§112 Rejection of the Claims

Claims 1-23 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. This rejection is respectfully traversed.

The Examiner has objected to the use of the term “comprising” in the definition of the “heterocyclic ring” as it allegedly includes limitations that are not recited in the claim. The claim has been clarified by amending the phrase to recite “. . . a 5- or 6-membered heterocyclic ring having 1-3 N(R⁸), S or nonperoxide O . . .” This amendment is made to clarify the claim and is not intended to narrow the scope of the definition.

Applicants note that “heterocyclic ring” is a term that is well known in the art. The language “a 5- or 6-membered heterocyclic ring having 1-3 N(R⁸), S or nonperoxide O” indicates that this Z group is a heterocyclic ring having 5 or 6 atoms, wherein at least one, or up to three, of the atoms are required to be a heteroatom in the ring. Applicants submit that those skilled in the art understand what this phrase includes. Thus, it is respectfully submitted that the use of this phrase is proper and the claim is definite.

The Examiner has objected to the moiety “an amino acid ester of (ω-(HO)(C₂-C₄))alkoxy” as allegedly it is not an art-recognized moiety. Further, he alleges that there is no description of this moiety in terms of structure or function. Applicants note that the terms “amino acid” and “ester” are terms that are well known in the art. This moiety defines a group that is the product of a reaction of an amino acid with a compound of formula (I) having the appropriate alcohol group to form the recited ester. Applicants submit that the structure and function of this moiety is understood by those skilled in the art. Thus, it is respectfully submitted that the use of this term is proper and the claim is definite.

The Examiner has objected to claim 5 for a lack of antecedent basis because the group OCH₂CH₂N(CH₃)₃⁺ is not recited in claim 1. As amended, claim 1 recites this group as a Z substituent. It is respectfully requested this objection be withdrawn.

Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 112 is requested.

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§102 Rejection of the Claims

Claim 1 was rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Brocks, et al. (Drug Disposition - Clinical. Pharmacokinetics, 26(4), 1994, 259-274). This rejection is respectfully traversed.

Claim 1 recites that Y is either $(CH_2)_{1-3}$ or $(CH_2)_{1-3}SO_2$. Brooks does not disclose or suggest a compound comprising a Y group according to the present claims. Thus, the Brooks does not anticipate claim 1. The examiner is requested to note that the amendment of claim 1 as presented herein does not surrender any equivalent to which the other substituents may be entitled.

Claim 1 was rejected under 35 USC § 102(e) as being allegedly anticipated by Vigano, et al. (U.S. Patent No. 6,066,741). This rejection is respectfully traversed.

Claim 1 recites that Y is either $(CH_2)_{1-3}$ or $(CH_2)_{1-3}SO_2$. The '741 patent does not disclose or suggest a compound comprising a Y group according to the present claims. As a result, the claim does not include any compounds disclosed in the '741 patent. Thus, the '741 patent does not anticipate claim 1.

Accordingly, reconsideration and withdrawal of the rejection of claim 1 under 35 U.S.C. § 102(b) is proper and is requested.

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Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney ((612) 373-6968) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date

Sept 3, 2002

By

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, Washington, D.C. 20231, on this 3rd day of September, 2002.

Name

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Signature

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